

R E M A R K S

It is respectfully requested that the Examiner enter and consider Claims 1, 9 and 10 in the version set forth in Appendix II attached to this paper. Accordingly, Claims 2 to 8 and 11 are canceled, and Claim 1 is amended as indicated in the marked-up version set forth in Appendix I to include the limitations of Claim 11. No new matter has been added.

Entry and consideration of the foregoing amendment is deemed appropriate at this stage of proceedings for due process for the following reasons:

On the one hand, the Examiner acknowledged that applicants' claims as submitted in paper No. 07 meet the unity of invention requirement of PCT Rule 13 which governs restriction of the present application and, correspondingly, the Examiner's authority to withdraw claims from further consideration. On the other hand, however, the Examiner

- (a) indicates in No. 4) of form PTO-326 that Claims 6 and 11 remain withdrawn from consideration in this application¹⁾, and
- (b) states on page 2 of the detailed action that Claim 11 is deemed to relate to a non-elected species and remains withdrawn because "first, there are no clear definitions for X¹ and X⁵; the expression 5-F for X² is unclear" (emphasis original).

It is respectfully noted that the unity of invention provisions which govern the restriction of the examination of the application contain nothing which would authorize a restriction to elected species in a case where the unity of invention requirement is met. Since the Examiner acknowledged that those requirements are met in the present case, a withdrawal of Claim 11 from further consideration in the application merely because it is deemed to relate to a non-elected species²⁾ is in error.

Furthermore, the Examiner's argument why Claim 11 remains withdrawn from further consideration implicates issues of clarity rather

- 1) In light of the Examiner's remarks in the detailed action, applicants assume that the indication that Claim 6 remains withdrawn from further consideration in this application is due to an inadvertent error.
- 2) As submitted by applicants in their reply dated June 26, 2002 (date of the Certificate of Mailing), the position that Claim 11 relates to a non elected species is not shared by applicants (note pages 6 and 7 of Paper No. 07).

than unity of invention. "clarity" issues, or definiteness of claim language, is however governed by the provisions of Section 112, ¶2, and not connected with restriction practice under either the U.S. national standards or the PCT standards. An issue concerning definiteness of claim language therefore does not authorize the Examiner to withdraw a claim from consideration.

In light of the Examiner's finding that the unity of invention requirements are met by the claimed subject matter, and since neither the Examiner's assertion that Claim 11 relates to a non-elected species nor the Examiner's remarks that Claim 11 is unclear have a bearing on unity of invention, the Examiner's withdrawal of Claim 11 from consideration is deemed to be improper.

To the extent that the Examiner contends that the language of applicants' Claim 11 lacks "clarity" or definiteness, a rejection under Section 112, ¶2, should have been made by the Examiner. Since Claim 11 had previously not been included by the Examiner in the consideration, such a rejection would have necessitated that a non-final action is issued. In this context it is respectfully noted that applicants submitted Claim 11 in their reply dated November 26, 2001 (*date of the Certificate of Mailing*), and Claim 11 was before the Examiner at the time the non-final action dated April 23, 2002, issued. Furthermore, the changes which applicants subsequently made in the wording of Claim 11 (*reply dated June 26, 2002, date of the Certificate of Mailing*) did not touch on the issues addressed in the Examiner's remarks in the final action.

A final action is issued prematurely if it raises a new issue of patentability which could have been raised by an examiner in the preceding proceedings. The fact that an examiner chose to refuse consideration of a claim which is timely submitted by an applicant does not mean that the issue of patentability could not have been raised earlier. Where a claim which was previously withdrawn from consideration is considered for the first time by an examiner in a second action, such action cannot reasonably be made final if the examiner deems the newly considered claim to be unpatentable under the pertinent provisions of the Patent Act. Under those circumstances, the material issue(s) of patentability concerning the newly considered claim are new issues, and it is premature to issue a Office action raising such new issues as a final action. It would appear to be arbitrary and capricious to deny an applicant who timely presented a

claim the opportunity to fully address such new issues of patentability.

It is further respectfully submitted that Claim 11 as submitted in Paper No. 05 or as subsequently amended is not deemed to be defective under the provisions of Section 112, ¶2. Claim 11 depends upon Claim 1, and the limitations set forth in Claim 1 are therefore incorporated by reference. Since the variables X^1 and X^5 are fully and clearly defined in Claim 1, the Examiner's position that "there are no clear definitions for X^1 and X^2 " in Claim 11 is deemed to be in error. Also, the variable X^2 is indicated in formula (II) as being bonded to the carbon ring atom in position 5 of the phenyl ring of formula (II). Accordingly, the indication in Claim 11 that " X^2 is 5-F" (*emphasis added*) is -although redundant- fully consistent with formula (II). Since there is no discrepancy between formula (II) and the definition of X^2 , the subject matter defined in Claim 11 is not rendered indefinite due to the redundancy. The Examiner's reasons why Claim 11 is unclear are therefore not deemed to be well taken.

In light of the foregoing, it is respectfully requested that the Examiner either withdraw the finality of the most recent Office action, or that the foregoing amendment be entered and be given full consideration by the Examiner. Favorable action is solicited.

The Examiner has maintained the rejection of Claims 1 to 10 under 35 U.S.C. §112, ¶1, asserting that the claimed subject matter is insufficiently enabled by the detailed description of the invention in the application. Favorable reconsideration of the Examiner's position and withdrawal of the respective rejection is respectfully solicited in light of the following.

The enablement requirement refers to the requirement of 35 U.S.C. 112, ¶1, that the specification describe how to make and how to use the invention. The standard is the person of ordinary skill in the art, and the invention which has to be enabled is the invention defined by the claim(s) of the application. The information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention. Detailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention. The test of enablement is not whether any exper-

imentation is necessary, but whether, if experimentation is necessary, such experimentation goes beyond routine efforts it is therefore undue³⁾.

There are many factors to be considered in the determination whether there is sufficient evidence to support a conclusion that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". The factors which have to be considered before a conclusion of lack of enablement is reached include⁴⁾:

- (a) the breadth of the claims;
- (b) the nature of the invention;
- (c) the state of the prior art;
- (d) the level of skill of one having ordinary skill in the art;
- (e) the level of predictability in the art;
- (f) the amount of direction provided by the inventor;
- (g) the existence of working examples; and
- (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In *In re Wands*, the Court reversed the PTO's determination that claims directed to methods for detection of hepatitis B surface antigens did not satisfy the enablement requirement. The Court noted that there was no disagreement as to the facts, but merely a disagreement as to the interpretation of the data and the conclusion to be made from the facts⁵⁾. The Court held that the specification was enabling with respect to the claims at issue and found that⁶⁾

- "there was considerable direction and guidance" in the specification;
- there was "a high level of skill in the art at the time the application was filed;" and
- "all of the methods needed to practice the invention were well known" at the time the application was filed.

After considering all the factors related to the enablement issue, the Court concluded that no more than routine experimentation was

3) *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976)

4) *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (CAFC 1988)

5) *In re Wands*, 858 F.2d at 736-40, 8 USPQ2d at 1403-07.

6) *In re Wands*, 858 F.2d at 740, 8 USPQ2d at 1406.

required to obtain antibodies needed to practice the claimed invention⁷⁾, which did not amount to undue experimentation for a person having ordinary skill in the pertinent technology.

It is improper to conclude that a disclosure is not enabling based on an analysis of only one or some of the above factors while ignoring one or more of the others. The examiner's analysis must consider all the evidence related to each of these factors, and any conclusion of non-enablement must be based on the evidence as a whole⁸⁾. In the present case, the Examiner clearly fails to take factors such as

- the state of the prior art;
- the level of skill of a person of ordinary skill in the art; and
- the amount of guidance and direction provided by applicants in the application,

into consideration. However, whether the specification would have been enabling as of the filing date involves consideration of the nature of the invention, the state of the prior art, and the level of skill in the art. The initial inquiry is into the nature of the invention, i.e., the subject matter to which the claimed invention pertains. The nature of the invention becomes the backdrop to determine the state of the art and the level of skill possessed by one skilled in the art.

The state of the prior art is what one skilled in the art would have known, at the time the application was filed, about the subject matter to which the claimed invention pertains. The relative skill of those in the art refers to the skill of those in the art in relation to the subject matter to which the claimed invention pertains at the time the application was filed. The state of the prior art in this case, therefore, includes at the very least the teachings which are, for example, provided by *Schwalge et al.* (US 5,972,941) and by *Kasahara et al.* (US 5,847,005) concerning

- the availability of the referenced compounds and their effectiveness against harmful fungi,
- the methods of applying those compounds in effective amounts, and
- the nature of the harmful fungi,

7) *In re Wands*, 858 F.2d at 740, 8 USPQ2d at 1407.

8) *In re Wands*, 858 F.2d at 737, 740, 8 USPQ2d at 1404, 1407.

as well as the teachings which are, for example, provided by **Schwalge et al.** concerning

- the evaluation of the fungicidal efficacy of an active compound⁹⁾, and
- the evaluation of synergistic fungicidal properties in accordance with the calculation of **Colby** (*Weeds* 15, 20-22 (1967)).

The state of the prior art provides evidence for the degree of predictability in the art and is related to the amount of direction or guidance needed in the specification as filed to meet the enablement requirement. The specification need not disclose, let alone explain, what is well-known to those skilled in the art. Information which is well-known and already available to the public is preferably omitted¹⁰⁾. In light of the state of the art as, for example, provided by **Schwalge et al.** and by **Kasahara et al.**, a person of ordinary skill in the fungicidal art requires guidance as to

- which compounds to select to arrive at a fungicidal action which is synergistically enhanced;
- which application rate to select for each of the compounds to arrive at the synergistic fungicidal action; and
- which ratios to use when combining the selected compounds,

in order to be enabled to make and/or use applicants' invention commensurate in scope with the claims. The information necessary for a person of ordinary skill to select the requisite compounds is provided on page 2, indicated line 13, to page 10, indicated line 47, of the application. Guidance as concerns the application rate for the compounds is provided by applicants' disclosure on page 12, indicated lines 15 to 17 (re compounds (I)), and indicated lines 19 to 21 (re compounds (II)), of the application. Additionally, applicants' provide guidance on the amount of the combination which is to be applied (ie. page 12, indicated lines 10 to 13, and indicated lines 23 to 25, of the application), and the ratio in which the active constituents of the

9) The fact that **Schwalge et al.** merely state "Evaluation was by determining the infected leaf areas in percent. These percentages were converted into efficacies" indicates that **Schwalge et al.** consider further information on the calculation of efficacies unnecessary for being within the technical background knowledge. Besides, applicants' disclosure provides the information on page 15, indicated line 31 et seq., of the application.

10) In re Buchner, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (CAFC 1991); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 USPQ 81, 94 (CAFC 1986), cert. denied, 480 U.S. 947 (1987); and Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1463, 221 USPQ 481, 489 (CAFC 1984).

composition are to be combined (ie. page 11, indicated lines 5 to 8, of the application). Given the amount of guidance provided by applicants' disclosure and the knowledge already available to a person of ordinary skill, no more than routine efforts are necessary to make the synergistic combination of the active compounds, and to apply it to the harmful fungi.

A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, ¶1. In order to make a rejection, the examiner has the initial burden to establish that there is a reason to doubt the objective truth of the statements contained in the application¹¹). Only where sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use is proper¹²). As stated by the Court in *In re Marzocchi*, "it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure"¹³).

The minimal requirement is for the examiner to give reasons for the uncertainty of the enablement from the standpoint of a person having ordinary skill in the pertinent art¹⁴). This standard is applicable even when there is no evidence in the record of operability

11) *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (CAFC 1993) (examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure). Also, more than the general allegation of "unpredictability in the art" is needed to substantiate doubts since the inventors attest to the truth and accuracy of the statements made in the application in their declaration "We (I) declare that all statements made herein of our (my) own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon."

12) *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971).

13) *In re Marzocchi*, 439 F.2d at 224, 169 USPQ at 370.

14) *In re Bowen*, 492 F.2d 859, 862-63, 181 USPQ 48, 51 (CCPA 1974).

without undue experimentation beyond the disclosed embodiments¹⁵). The Examiner's position is, however, not taken from the standpoint of a person having ordinary skill in the pertinent art, as is apparent from the criticism concerning the degree of action or efficacy of fungicides, as well as the assertion that results presented by applicants which make use of the calculation according to Colby's formula fail to show synergism¹⁶). In this context it is also respectfully noted that the Examiner's reliance on the Court's holding in *In re Borkowski*¹⁷) is deemed to be misplaced. The Court in *In re Borkowski* did not express the opinion, or even implied, that an applicant has to burden to explain to the examiner the state of the art¹⁸). Rather, the Court held that an applicant who offers notebook pages as proof of a reduction to practice prior to the earliest filing date of an application (ie. a declaration pursuant to Rule 131 rather than Rule 132) has the burden to explain the contents of the notebook pages and to explain how such pages establish, or contribute to establishing, the earlier date of invention sought¹⁹).

In light of the foregoing, applicants' detailed description of the invention in the application fully meets the enablement requirement of Section 112, ¶1, of the Patent Act. Also, the Examiner has failed to establish that there is reasonable doubt that a person of ordinary skill in the art would require more than routine experimentation to make and/or use applicants' invention. Withdrawal of the rejection is therefore solicited.

The Examiner has maintained the rejection of Claims 1 to 10 under 35 U.S.C. §103(a) as being unpatentable in light of the disclosure of

15) See e.g. *In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (CAFC 1995), citing *In re Bundy*, 642 F.2d 430, 433, 209 USPQ 48, 51 (CCPA 1981).

16) At the very least *Schwalge et al.*'s disclosure corroborates that a person of ordinary skill in the fungicidal art is well aware of the significance of a degree of action or efficacy and the significance of the difference between expected efficacy and calculated efficacy, and that a person of ordinary skill is equally well aware of how such data are obtained.

17) 505 F.2d 713, 184 USPQ 29 (CCPA 1974)

18) Applicants' disclosure provides the Abbot calculation which is routinely used in the fungicidal art to establish the efficacy of a fungicide (page 15, indicated line 31 et seq., of the application), as well as the Colby calculation which is routinely used in the fungicidal art to establish synergism (page 15, indicated line 46 et seq., of the application). Applicants further submitted an explanation of the rationale underlying the calculation in accordance with Colby's formula (pages 3 and 4, bridging paragraph, of Paper No. 07).

19) *In re Borkowski*, 184 USPQ at 33.

— **Schwalg et al.** (US 5,972,941) and **Kasahara et al.** (US 5,847,005). Favorable reconsideration of the Examiner's position and withdrawal of the respective rejection is respectfully solicited in light of the following.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success, and, finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Further, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and cannot be based on applicant's disclosure²⁰). Also, the level of skill in the art cannot be relied upon to provide the suggestion to combine references²¹). The disclosures of **Schwalge et al.** and **Kasahara et al.**, alone or in combination with one another, fail to teach or suggest all the claim limitations since they fail to teach or fairly suggest a synergistically effective combination of a compound (I) and a compound of formula (II)²²). The teachings of **Schwalge et al.** and **Kasahara et al.** therefore fail to establish that applicants' invention was *prima facie* obvious under the provisions of Section 103(a) at the time the application was filed. Withdrawal of the rejection is therefore solicited.

In light of the foregoing and the attached, the subject matter defined in applicants' claims is deemed to be patentable under the pertinent provisions, and the application meets the requirements relating to the form or contents which are applicable in the present case. Allowance of the application is therefore deemed equitable.

20) In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (CAFC 1991)

21) Al-Site Corp. v. VSI Int'l Inc., 174 F.3d 1308, 50 USPQ2d 1161, 1171 (CAFC 1999)

22) Note, for example, In re Luvisi, 342 F.2d 102, 144 USPQ 646 (CCPA 1965), where the Court stated "We do not accept the notion that every suggestion of synergism in the art coupled with a finding of synergism in the practice of the invention automatically compels a conclusion of obviousness". In the present case, the prior art fails to suggest synergism to arise from a combination of applicants' components (a) and (b). Accordingly, applicants' invention is further away from the state of the art than the invention of *Luvisi* considered by the Court.

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Respectfully submitted,

KEIL & WEINKAUF



Herbert B. Keil

Reg. No. 18,967

1350 Connecticut Ave, N.W.
Washington, D.C. 20036
(202) 659-0100

Encl.: THE CHANGES IN THE CLAIMS (Appendix I)
THE AMENDED CLAIMS (Appendix II)

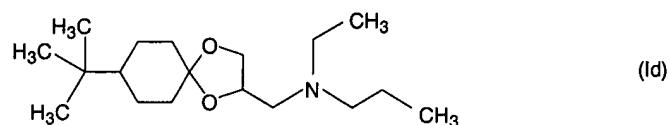
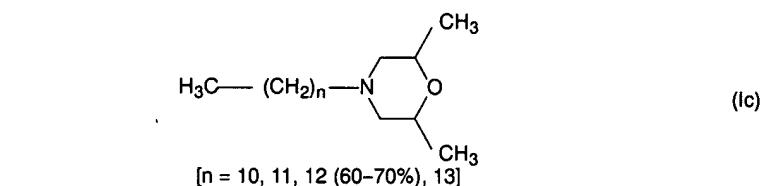
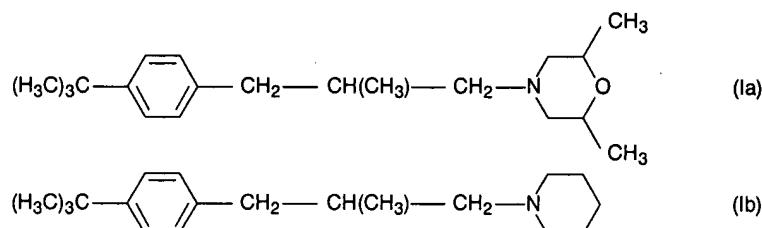
HBK/BAS

APPENDIX I:

THE CHANGES IN THE CLAIMS (version with markings, showing the changes made):

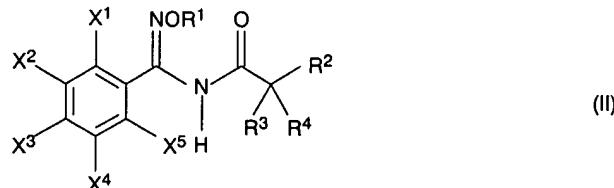
1. (twice amended) A fungicidal mixture, comprising as active components

a) a morpholine or piperidine derivative I selected from the group of the compounds Ia, Ib, Ic and Id



and

b) compounds of the formula II



where the substituents X¹ to X⁵ and R¹ to R⁴ are as defined below:

X¹ is C₁-C₄-haloalkyl, C₁-C₄-haloalkoxy or halogen;

X² [~~is~~] is fluorine,

X³ and X⁴ are each hydrogen,

X⁵ [are, independently of one another,] is hydrogen, halogen, C₁-C₄-alkyl, C₁-C₄-haloalkyl, C₁-C₄-alkoxy or C₁-C₄-haloalkoxy,

R¹ is [C₁-C₄-alkyl, C₂-C₆-alkenyl, C₂-C₆-alkynyl, C₁-C₄-alkyl-C₃-C₇-cycloalkyl, where these radicals may carry substituents

selected from the group consisting of halogen, cyano and C₁-C₄ alkoxy] methylenecyclopropyl,

R² is [a phenyl radical which may have one to three substituents selected from the group consisting of halogen, C₁-C₄ alkyl, C₁-C₄ alkoxy, C₁-C₄ haloalkyl, C₁-C₄ haloalkoxy, C₁-C₄ alkoxy-C₂-C₄ alkynyl] C₆H₅-CH₂,

R³ and R⁴ are[, independently of one another,] each hydrogen, [C₁-C₄ alkyl, C₁-C₄ alkoxy, C₁-C₄ alkylthio, N-C₁-C₄ alkylamino, C₁-C₄ haloalkyl or C₁-C₄ haloalkoxy]

in a synergistically effective amount.

Claims 2 to 8 and 11 have been canceled

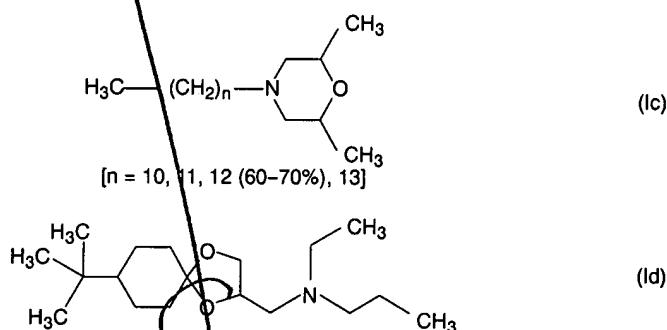
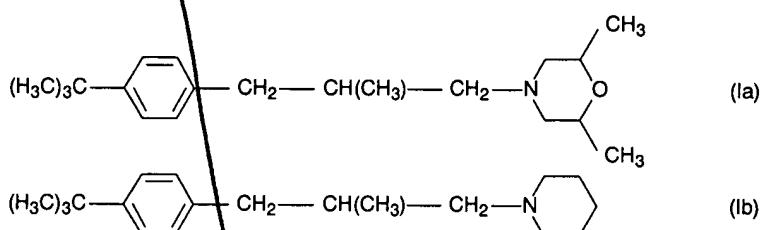
2. (canceled) A fungicidal mixture as defined in claim 1, where in the compounds II, R¹ is C₁-C₄ alkyl or C₁-C₄ alkylene-C₃-C₇ cycloalkyl.
3. (canceled) A fungicidal mixture as defined in claim 1, where in the compounds II, R² is phenyl which may be substituted by halogen, C₁-C₄ alkoxy or C₁-C₄ alkyl.
4. (canceled) A fungicidal mixture as defined in claim 1, where in the compounds II, R³ or R⁴ are hydrogen, fluorine, chlorine, methyl, ethyl, methoxy, thiomethyl or N-methyamino.
5. (canceled) A fungicidal mixture as defined in claim 1, where in the compounds II, x¹ is halo-C₁-C₆ alkyl, halo-C₁-C₆ alkoxy or halogen.
6. (canceled) A fungicidal mixture as defined in claim 1, where in the compounds II, x² or x³ are hydrogen or halogen.
7. (canceled) A fungicidal mixture as defined in claim 1, where in the compounds II, x⁴ is hydrogen, chlorine, fluorine, methoxy, ethoxy, trifluoromethyl or trifluoromethoxy.
8. (canceled) A fungicidal mixture as defined in claim 1, where in the compounds II, x⁵ is hydrogen, chlorine, fluorine, methoxy, ethoxy, trifluoromethyl or trifluoromethoxy.
11. (canceled) A fungicidal mixture as defined in claim 1, wherein in the compound of the formula II, R¹ is methylenecyclopropyl, x² is 5-F, x³ and x⁴ are each H, R² is C₆H₅-CH₂ and R³ and R⁴ are each H.

APPENDIX II:

THE AMENDED CLAIMS (clean version of all claims):

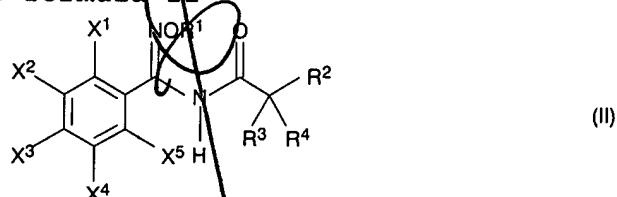
1. (twice amended) A fungicidal mixture, comprising as active components

a) a morpholine or piperidine derivative I selected from the group of the compounds Ia, Ib, Ic and Id



and

b) compounds of the formula III



where the substituents X^1 to X^5 and R^1 to R^4 are as defined below:

X^1 is $\text{C}_1\text{-C}_4\text{-haloalkyl}$, $\text{C}_1\text{-C}_4\text{-haloalkoxy}$ or halogen;

X^2 is fluorine,

X^3 and X^4 are each hydrogen,

X^5 is hydrogen, halogen, $\text{C}_1\text{-C}_4\text{-alkyl}$, $\text{C}_1\text{-C}_4\text{-haloalkyl}$, $\text{C}_1\text{-C}_4\text{-alkoxy}$ or $\text{C}_1\text{-C}_4\text{-haloalkoxy}$,

R^1 is methylenecyclopropyl,

R^2 is $\text{C}_6\text{H}_5\text{-CH}_2$,

R^3 and R^4 are each hydrogen,

in a synergistically effective amount.

P2

9. (amended) A fungicidal mixture as defined in claim 1, which is conditioned in two parts, where one part comprises one or more compounds I in a solid or liquid carrier and the other part comprises one or more compounds of the formula II in a solid or liquid carrier.
10. (twice amended) A method for controlling phytopathogenic fungi, which comprises treating the fungi, their habitat or materials, plants, seeds, soils, areas ~~or~~ spaces to be protected against fungal attack with an effective amount of the fungicidal mixture as defined in claim 1, where the compounds I and one or more compounds of the formulae II can be applied simultaneously, that is either together or separately, or successively.